IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9200

Bartle, J. January 29, 2014

Courtney J. Solberg ("Ms. Solberg" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2010, claimant submitted a completed Green Form to the Trust signed by her attesting physician, James P. Olson, M.D. Based on an echocardiogram dated March 27, 2000, Dr. Olson attested in Part II of Ms. Solberg's Green Form that claimant had severe mitral regurgitation, surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, New York Heart Association Functional Class III symptoms, and a left ventricular ejection fraction < 40% at any time six months or later after valvular repair or

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2. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who has factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

replacement surgery.[3] Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits in the amount of $1,719,696.[4]

Dr. Olson also attested in claimant's Green Form that Ms. Solberg did not suffer from mitral valve prolapse. Under the Settlement Agreement, the presence of mitral valve prolapse requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b).

In the report of claimant's September 17, 2007 echocardiogram, the only echocardiogram conducted six months or later after claimant's mitral valve surgery, Dr. Olson stated that Ms. Solberg's "[e]jection fraction is estimated at 50%." An ejection fraction is considered reduced for purposes of a Level V

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3. Dr. Olson also attested that claimant suffered from mild aortic regurgitation; bacterial endocarditis associated with either mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation; an abnormal left ventricular dimension; a reduced ejection fraction in the range of 30% to 34% prior to claimant's mitral valve surgery; and a stroke due to (a) bacterial endocarditis contracted after use of Pondimin® and/or Redux™, or (b) chronic atrial fibrillation with left atrial enlargement as defined in Green Form Question F.5., or (c) valvular repair and/or replacement surgery that resulted in a permanent condition that meets the criteria for Functional Level III of the AHA Stroke Outcome Classification System, determined six months or later after the event. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for payment at Matrix Levels III or IV, has New York Heart Association Functional Class III or Class IV symptoms, underwent surgery to repair or replace the aortic and/or mitral valve(s), and had a left ventricular ejection fraction of less than 40% six months or later after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)ii).

claim if it is measured as less than 40% six months or more after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)(ii)(d).

In May, 2011, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Parmar determined that there was a reasonable medical basis for Dr. Olson's findings that claimant had severe mitral regurgitation and surgery to replace her mitral valve. Dr. Parmar, however, determined that there was no reasonable medical basis for Dr. Olson's finding that claimant had an ejection fraction of less than 40% six months or more after claimant's mitral valve surgery. In particular, Dr. Parmar concluded: "The surgery was done 10/26/05. I reviewed multiple [echocardiograms]. The [echocardiogram] disc dated 9-17-07 shows preserved [left ventricular] systolic function [with] [ejection fraction] of 50%. I believe the [ejection fraction] is >40% by [echocardiogram] greater [than] 6 months after surgery."[5]

In addition, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Olson's findings that claimant did not have mitral valve prolapse. Specifically, Dr. Parmar stated:

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5. In audit, Dr. Parmar also concluded that there was no reasonable medical basis for Dr. Olson's finding that claimant suffered from New York Heart Association Functional Class III symptoms. Given our resolution with regard to claimant's mitral valve prolapse, we need not address the issue of New York Heart Association Functional Class symptoms.

> I reviewed multiple [transthoracic echocardiograms] and [transesophageal echocardiograms].
>
> The [transesophageal echocardiogram] dated 3/27/00 shows preserved [left ventricular] systolic function, myxomatous mitral valve with [mitral valve] prolapse and associated severe [mitral regurgitation].
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> The [transthoracic echocardiogram] dated 10/08/05 shows preserved [left ventricular] systolic function with mitral valve prolapse and severe [mitral regurgitation]. This [transthoracic echocardiogram] shows a thickened [mitral valve] with an echo density on the anterior leaflet with some degree of mobility.
>
> This could be consistent with vegetation or a torn chordae. I believe that this patient had a classic myxomatous mitral valve with [mitral valve] prolapse and may well have had a torn chordae as well, along with associated severe [mitral regurgitation].[6]

Based on Dr. Parmar's findings, and the Trust's determination that Ms. Solberg had not demonstrated that she ingested Diet Drugs for 61 days or more, it issued a post-audit determination that Ms. Solberg was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested the Trust's determination with respect to her ingestion of Diet

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6. Dr. Parmar also determined that there was no reasonable medical basis for Dr. Olson's representation that Ms. Solberg did not suffer from chordae tendineae rupture. Under the Settlement Agreement, the presence of chordae tendineae rupture also requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)c). Given our resolution with regard to claimant's mitral valve prolapse, we need not address the issue of chordae tendineae rupture.

Drugs.[7] The Trust subsequently issued a revised post-audit determination accepting Ms. Solberg's proof of Diet Drug ingestion for 61 days or more but again determining that she was entitled only to Matrix B-1, Level III benefits. Pursuant to the Audit Rules, Ms. Solberg contested this adverse determination.

In contest, claimant argued that there was a reasonable medical basis for finding that her ejection fraction was less than 40% six months or later after her mitral valve surgery.[8] Claimant asserted that, "when rating ejection fractions, physicians give the benefit of the doubt to the next highest percentage (ex., 37% or 38% would be reported as 35%-40% or 40% maximum." Thus, according to claimant, "it is logical to assume that Ms. Solberg's ejection fracture [sic] percentage was lower than 40%."[9] Claimant also requested that the Trust "reconsider

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Solberg's claim.

8. In contest, claimant submitted a number of medical records, including but not limited to: (1) the handwritten notes of claimant's February 7, 2006 echocardiogram, which lists an estimated ejection fraction of 38% (although an additional handwritten note states "45-50% vis. est."); (2) a Progress Record from a March 24, 2006 appointment with Steven E. Miller, M.D., which notes an ejection fraction of 40%; and (3) a report of a March 24, 2006 stress test for Ms. Solberg, which stated an ejection fraction of 36%.

9. Claimant did not submit any medical documents or other

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[its] position with regard to Ms. Solberg's placement on the B Matrix."

The Trust then issued a final post-audit determination again determining that Ms. Solberg was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Solberg's claim should be paid. On December 27, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8744 (Dec. 27, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 21, 2012. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust

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9. (...continued)
supporting materials for this assertion. This assertion also is contradicted by the fact that, in some of the medical records submitted by claimant, a specific ejection fraction percentage was listed by the physician. In any event, the court cannot accept a statement based on speculation without any medical support.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through
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and claimant have had the opportunity to develop the show cause record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there was a reasonable medical basis for the attesting physician's findings that claimant had a left ventricular ejection fraction less than 40% at any time six months or later after valvular repair or replacement surgery and that claimant did not have mitral valve prolapse as defined in the Settlement Agreement. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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10. (...continued)
the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Solberg argues that there is a reasonable medical basis for the attesting physician's Green Form representation that she suffered an ejection fraction of less than 40% six months or later after her mitral valve surgery because, although claimant did not have an echocardiogram performed exactly six months after her mitral valve surgery, her attesting physician "made the reasonable and medically sound decision to reply upon the medical evidence gathered five months post-surgery and extrapolate his conclusion about her condition at six months post-surgery from such testing." Thus, according to claimant, the attesting physician's finding that claimant had an ejection fraction less than 40% six months or later after her mitral valve surgery "is supported by the medical evidence demonstrating that her ejection fraction was only 36% at five months post-operation."

Claimant also argues that she has established a reasonable medical basis for the attesting physician's finding that she did not have mitral valve prolapse as defined in the Settlement Agreement because the auditing cardiologist's finding is contradicted by the attesting physician and the cardiologists who reviewed claimant's numerous echocardiograms over an almost five-year period. In particular, claimant asserts that the attesting physician's finding as to mitral valve prolapse is supported by the absence of a notation of mitral valve prolapse in numerous echocardiograms.

In response, the Trust argues that Dr. Olson's finding of a left ventricular ejection fraction less than 40% six months after valvular repair or replacement surgery lacks a reasonable medical basis because the medical records relied upon by claimant "all fall within the six month period following her October 26, 2005 mitral valve surgery." (Emphasis omitted). The Trust also asserts that, based on these records and claimant's September 17, 2007 echocardiogram, the auditing cardiologist correctly concluded that claimant did not have an ejection fraction of less than 40% six months or later after her mitral valve surgery. In addition, the Trust also contends that claimant did not establish a reasonable medical basis for the attesting physician's finding that claimant did not have mitral valve prolapse because, as conceded by claimant, certain of her medical records note the existence of mitral valve prolapse. The Trust further argues that the mere fact that a number of different cardiologists reviewed clamant's echocardiograms and did not note the presence or absence of mitral valve prolapse does not establish a reasonable medical basis for her claim. Finally, the Trust notes that claimant did not submit a statement from any physician rebutting the findings of the auditing cardiologist as to claimant's ejection fraction six months or later after her mitral valve surgery or as to the presence of mitral valve prolapse.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiograms and concluded that there was no

reasonable medical basis for the attesting physician's finding that claimant suffered from a left ventricular ejection fraction less than 40% six months or later after valvular repair or replacement surgery. In particular, Dr. Abramson determined that:

> This claimant had a normal ejection fraction before mitral valve surgery. It is common for the systolic function to decrease immediately after mitral valve surgery, but it should gradually increase over time. This claimant's ejection fraction decreased immediately post-operatively (ejection fraction of 40-45% on the echocardiograms from 11/28/05, 2/07/06, 3/24/06). She did not have an echocardiogram again until 9/17/07 which revealed an ejection fraction of 45-50%. Since there is no echocardiographic evidence of having an ejection fraction <40% less than five months post-operatively, and her ejection fraction continues to improve post-operatively, there is no reasonable medical basis for the Attesting Physician's answer that this claimant has an ejection fraction less than 40% greater than 6 months after valve replacement surgery.

Dr. Abramson also concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Solberg did not have mitral valve prolapse. Specifically, Dr. Abramson stated, in relevant part, that:

> This claimant does have mitral valve prolapse of the anterior mitral leaflet based on the [transesophageal echocardiogram] of attestation dated 3/27/00. The thickened anterior leaflet is displaced more than 2 mm into the left atrium during systole. There is also a suggestion of a cleft in the anterior mitral leaflet, which is a congenital cardiac abnormality found frequently in patients with Down syndrome. Dr. John C. Vanderwoude, the pathologist who

> examined the mitral leaflet which was removed during surgery found a "congenital cleft, anterior leaflet of the anterior mitral valve" and an "almost complete raphe consistent with the Down syndrome." There is no reasonable medical basis for the Attesting Physician's answer that this claimant does not have mitral valve prolapse.[11]

In response to the Technical Advisor report, claimant argues that the Technical Advisor's finding regarding the presence of mitral valve prolapse should be disregarded because "[o]ther cardiologists have reviewed the same echocardiograms and did not [find] mitral valve prolapse."

After reviewing the entire Show Cause Record, we find that claimant has failed to establish a reasonable medical basis for her claim. First, claimant has failed to meet her burden with respect to establishing a reasonable medical basis for the attesting physician's Green Form representation that Ms. Solberg had an ejection fraction of less than 40% six months or later after valvular repair or replacement surgery. As an initial matter, we previously have rejected the argument that a claimant may rely solely on records of medical procedures performed within the six month period after her mitral valve surgery to establish an ejection fraction six months or more after surgery. See, e.g., Mem. in Supp. of PTO No. 8976, at 8 n.11 (Nov. 28, 2012).

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11. Dr. Abramson also concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had New York Heart Association Functional Class III Symptoms but that there was a reasonable medical basis for the attesting physician's finding that claimant did not have chordae tendineae rupture.

In any event, a number of the reports for the echocardiograms performed in the six months following Ms. Solberg's surgery indicate that her ejection fraction was at least 40%, and Dr. Abramson reviewed claimant's November 28, 2005, February 7, 2006, and March 24, 2006 echocardiograms and determined each demonstrated an ejection fraction between 40% and 45%. In addition, Dr. Abramson noted that "[i]t is common for the systolic function to decrease immediately after mitral valve surgery, but it should gradually increase over time."[12] Moreover, claimant does not dispute that her ejection fraction was greater than 40% on the September 17, 2007 echocardiogram, the only echocardiogram that was performed more than six months following claimant's surgery. Under the circumstances of this case, claimant has failed to establish a reasonable medical basis for her attesting physician's finding that she suffered from an ejection fraction less than 40% six months or later after her mitral valve surgery.

Claimant also has not satisfied her burden of establishing that there was a reasonable medical basis for Dr. Olson's finding that she did not have mitral valve prolapse. As noted, the Settlement Agreement requires that a claim for damage to the mitral valve be reduced to the B Matrix if he or she had mitral valve prolapse. Settlement Agreement

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12. Despite submitting a response to the Technical Advisor Report, claimant does not substantively challenge Dr. Abramson's findings in this regard.

§ IV.B.2.d.(2)(c)ii)b). Both the auditing cardiologist and the Technical Advisor specifically found that numerous echocardiograms of claimant revealed the presence of mitral valve prolapse as defined in the Settlement Agreement.

Rather than respond to these findings, claimant instead argues only that there was a reasonable medical basis for the attesting physician's findings because virtually all of claimant's echocardiogram reports fail to mention the presence of mitral valve prolapse.[13] The mere absence of a notation of a specific medical condition in a report, however, is insufficient to satisfy a claimant's burden of proof where there has been a specific determination by both the auditing cardiologist and the Technical Advisor as to the presence of mitral valve prolapse on an echocardiogram.[14] Claimant never identified any particular error with the findings of the auditing cardiologist and the Technical Advisor as to the presence of mitral valve prolapse as defined by the Settlement Agreement. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

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13. The Show Cause record also contains affidavits of Frederic Van Dis, M.D., who reviewed claimant's March 20, 2000 and March 27, 2000 echocardiograms. In his echocardiogram report of claimant's March 20, 2000 echocardiogram, Dr. Van Dis specifically stated that claimant had a "[m]ildly thickened mitral valve without evidence of mitral valve prolapse."

14. This is particularly true as claimant acknowledged that several of her medical records did, in fact, note the presence of mitral valve prolapse.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for her claim for Matrix A-1, Level V benefits. Therefore, we will affirm the Trust's denial of Ms. Solberg's claim for Level V Matrix Benefits as well as her claim for benefits on Matrix A.